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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/179,188	10/27/1998	TOSHINARI SAKURAI	KAS-125	5396

7590 07/08/2002  
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EXAMINER

NAFF, DAVID M

ART UNIT PAPER NUMBER

1651

DATE MAILED: 07/08/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/17/188

Applicant(s)

Satura: JHL

Examiner

Halt

Group Art Unit

1657

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 7/17/01 + 10/17/01
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 20-32 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 20-32 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 19 + 22 (filed 7/17 + 12/14/01)
  - ☐ Interview Summary, PTO-413
  - ☐ Notice of Informal Patent Application, PTO-152
  - ☐ Other \_\_\_\_\_
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

Office Action Summary

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/17/01 has been entered.

The amendment filed 10/17/01 has been entered. The amendment canceled claims 1-12 and 16-19, and added new claims 20-32.

10 Claims examined on the merits are 20-32 which are all claims in the application.

The drawing corrections filed 10/17/01 are acceptable.

The copending applications listed on form PTO-1449 of 12/14/01 have been considered, but have been lined through since the applications are not published, and are not listed on U.S. Patents as references cited.

15 Document AR on form PTO-1449 of 12/14/01 has not been considered and lined through since a copy of the document did not accompany the form.

The disclosure is objected to because of the following informalities: lines 1-4 on page 12 should be deleted, and reinserted below "DESCRIPTION OF THE PREFERRED EMBODIMENT" on page 13, i.e. between lines 10 and 11 on page 13, since lines 1-4 are not related to the brief description of the drawings. Additionally, to be clear, lines 1-4 should be amended as follows: line 1, cancel "These and other", and change "features" to -- Features --; line 2, before "apparent" insert -- further --; and line 4, change the comma to a period, and cancel "in which:".

Appropriate correction is required.

Claims 20-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to disclose carrying out steps separate from each other as required in the last two lines of claims 20 and 25, and separate preparation of solutions as required in the last two lines of claim 27.

The specificating fails to disclose "destroying a nucleic acid-bearing material" as required in line 3 of claims 20 and 25, and bridging lines 3 and 4 of claims 26, 27 and 32. The specification describes only releasing nucleic acids from a nucleic acid-bearing material.

The specification fails to disclose a method as required by claim 26 for recovering nucleic acids from a nucleic acid-bearing material. Providing first, second and third solutions, and a solution containing an alcohol and a salt, and carrying out only steps of separating material containing adsorbed nucleic acids, eluding the adsorbed nucleic acids and removing alcohol and salt contained in the eluted nucleic acids is not disclosed in the specification. The specification discloses only methods of recovering nucleic acids from a nucleic acid-bearing material requiring six steps as set forth from page 6, line 5 from the bottom, to page 9, line 6.

The specification fails to describe a method of isolating an adsorbing solid phase to which nucleic acids are bonded as required by claims 27-32. There is no disclosure that the invention is to be a method of isolating a solid phase containing bonded nucleic acids instead of a method of recovering nucleic acids from a nucleic acid-bearing material. Additionally, there is no description of performing such a method by only preparing first, second and third solutions separately as required by claim 27, and by only providing a first solution and then carrying out two steps of transferring as in claim 32. As set forth above, the specification describes only methods requiring six steps for recovering nucleic acids from a nucleic acid-bearing material.

Claims 20-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15 The claims are confusing and unclear by failing to set forth clear, distinct and positive method steps that have a clear relationship to each other in providing a complete method. Claims 26-32 are additionally unclear by failing to set forth all steps needed for a complete method, and in claiming a methods not described in the specification.

20 Reciting "a step" followed by describing the function of the step is confusing, and makes metes and bounds of the claims unclear. The claims should set forth manipulations performed to carry out steps rather than requiring steps for performing functions.

In the last two lines of claims 20 and 25, the meaning and scope of conducting steps separately is uncertain. In what say are the steps

conducted separately? The specification fails to define conducting steps separately as compared to not conducting steps separately. Similarly, in the last two lines of claim 27, the meaning and scope of preparing solutions separately is uncertain since the specification fails to define preparing solutions separately as compared to not preparing solutions separately.

In lines 3, 7 and 21 of claim 20, and where recited in other claims, "destroying" is uncertain as to meaning and scope as it applies to the present invention. This term is normally not used in the context it is being used in the claims.

To overcome the above rejections, the following amendments are suggested.

Claim 20,

line 3, cancel "a step for destroying", and insert -- releasing nucleic acids from --;

line 4, cancel "release the nucleic acids therefrom in" and insert - and forming --, and after "solution" insert -- containing the released nucleic acids --;

line 5, cancel "a step for", cancel "a binding" and insert -- an --, after "accelerator" insert -- substance for binding the released nucleic acids to a solid phase --, and cancel "an" and insert -- the --;

line 6, cancel ", after the";

line 7, cancel "destroying step";

line 8, cancel "a step for", and cancel "containing" and insert -- contacting --;

line 9, after "accelerator" insert -- substance --;

line 10, cancel "thereby";

line 11, cancel ", after the adding step";

line 12, cancel "a step for";

5 line 13, cancel ", after the";

line 14, cancel "contacting step";

line 15, cancel "a step for";

line 16, cancel ", after the";

line 17, cancel "isolating step";

10 line 18, cancel "a step for";

line 19, cancel ", after the washing";

line 20, cancel "step";

lines 21 and 22, cancel the lines.

Claim 25, amend the claim in the same way as is suggested for claim

15 20 above.

Claims 26-32, cancel the claims.

Claims 20-32 are rejected under 35 U.S.C. 103(a) as being  
unpatentable over Boom et al (5,234,809) in view of Seligson et al  
(4,935,342).

20 The claims are drawn to methods of recovering nucleic acids from a  
nucleic acid-bearing material by carrying out separate steps of releasing  
the nucleic acids to obtain an aqueous solution containing the released  
nucleic acids, adding an accelerator for binding the nucleic acids to a  
solid phase, adsorbing the nucleic acids on a solid phase, isolating the

solid phase, washing the isolated solid phase, and eluting the nucleic acids from the solid phase.

Boom et al disclose purifying nucleic acids from a nucleic acid-containing starting material by mixing the starting material, a  
5 chaotropic substance and a nucleic acid binding solid phase, separating the solid phase with nucleic acid bound thereto, washing the solid phase, and eluting nucleic acids from the solid phase. For example, see col 2, lines 13-22, and claims 1 and 12. The solid phase may be a silicon  
10 dioxide containing material (col 2, lines 52-60), and the chaotropic substance may be guanidine hydrochloride (col 3, line 63). Washing can be with a salt containing solution and an alcohol containing solution (col 4, lines 20-30). Nucleic acids contained by the nucleic acid-containing material may be released by cell lysis (col 2, lines 43-46).

Seligson et al disclose a method purifying nucleic acids by  
15 providing an aqueous solution containing nucleic acids as a sample, adsorbing nucleic acids to an ion exchange column from the sample, washing with a chloride salt solution and eluting the nucleic acids (see claims). The salt may be sodium chloride (col 5, lines 60-65). To  
20 obtain the aqueous solution of nucleic acids that is applied to the column, nucleic acids are released from a starting material such as cells or viruses (col 8, lines 3-36) by contacting the cells or viruses with a lysing agent or detergent, and separating solids by centrifugation or  
filtration (col 8, lines 30-34) to obtain a supernatant that is an  
aqueous solution of nucleic acids in combination with water-soluble  
25 components of lysed cells or viruses.



When carrying out the nucleic acid purifying process of Boom et al, it would have been obvious to perform an initial step of releasing nucleic acids from cells or viruses to obtain an aqueous solution of nucleic acids for applying to the solid phase as suggested by Seligson et al since Boom et al disclose that starting material cells may be subjected to lysis (col 2, line 45), and since it would have been expected that nucleic acids bound within cells will be unavailable for adsorbing to the solid phase of Boom et al. It would have been further obvious to add the chaotropic substance of Boom et al to the aqueous solution of nucleic acid resulting from cell lysis before adding the aqueous solution to the solid phase since Boom et al combines the chaotropic substance, starting material and solid phase together so released nucleic acids will immediately bind to the solid phase. When not desiring this advantage, it would have been clearly obvious to add the chaotropic substance to the starting aqueous nucleic acid solution in a separate step. In regard to using a chloride in a washing solution as in claim 23, it would have been obvious to add a chloride salt to the washing of Boom et al to obtain the function of chloride salt for washing as disclosed by Seligson et al. Using potassium chloride or an acetate salt would have been a matter of obvious choice depending on individual preference and convenience since such salts are well known components of buffers, and the washing solution of Boom et al is a washing buffer (col 4, line 22). Acetate is a well known buffer component, and its use to produce the washing buffer would have been obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00

5 PM.

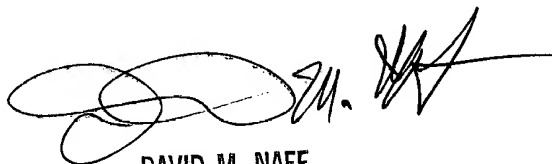
If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number  
10 (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist  
15 whose telephone number is (703) 308-0196.

20 DMN  
7/5/02

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 1651